

Donor History Questionnaire User Brochure

Purpose: The User Brochure was designed to aid the donor historian in determining if a prospective donor is eligible to donate. Each blood center must have a standard operating procedure (SOP) related to donor suitability to be used in conjunction with the User Brochure. The User Brochure does not replace an SOP for determining donor suitability. Both the User Brochure and the SOP must be available to staff performing health histories. Alternately, the User Brochure contents may be transcribed into the SOP.

Introduction: The Donor History Questionnaire (DHQ) must be administered on the date of donation. All prospective donors, including those that meet criteria for screening using the abbreviated DHQ, must read the Donor Educational Materials prior to completing the DHQ. They also must be given the Medication Deferral List, and a list of BSE countries to be used with the DHQ. As an alternative, one or all of the lists can be prominently displayed at the donation site for the donors' use while they are completing the DHQ. The DHQ was designed for self-administration by the donor, with follow-up review by a trained donor historian. All donors, including those that meet criteria for screening using the abbreviated DHQ, should be instructed to complete all questions on the questionnaire. A knowledgeable donor historian should be available to the prospective donor to answer any questions concerning eligibility or the donation process. Alternatively, the DHQ may be administered by a donor historian. The method of administration of the DHQ should be in accordance with the blood center's SOP. Blood collection facilities are reminded that donor screening is an active process involving open communication between donors and trained donor historians, and that donors should be encouraged to voice questions and concerns at any time during the screening and donation process.

Collection facilities using these screening materials should be aware that these materials were tested in English-speaking donor and non-donor groups and due to practical limitations could not be tested in all possible settings, including with non-English speaking donors.

DHQ Format: The DHQ questions were composed for ease of understanding by the prospective donor. The DHQ was evaluated in its current form for comprehension; therefore, the wording and the order of the questions should not be changed. Blood centers may choose to add local questions to the beginning or the end of the DHQ. The Educational Material and Medication Deferral List also must be used unabridged except for local additions. The questions are grouped by time period beginning with a question about "today" and ending with questions relating to "have you ever." **The entire DHQ must be completed before eligibility is determined.**

The DHQ and aDHQ use **capture questions** that may require donor historian intervention or follow-up. Capture questions are questions that cover a broad topic, and

when an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. Some follow-up questions are included in the User Brochure, but since specific donor eligibility criteria may vary from one blood center to another, an affirmative response to some questions may require consultation with the blood center's SOP. Blood centers may implement more restrictive deferral policies than described in the User Brochure per their local SOP.

Additionally, DHQ has several “**attention**” questions . An example of one of the attention questions is listed below.

In the past 6 weeks, have you been pregnant
or are you pregnant now? (Males check “I
am male”)

An inappropriate answer to the question would be a male answering “yes” or “no.” Each blood center must define the action of the donor historian when a donor inappropriately answers the attention questions.

Documentation: Information impacting donor suitability obtained during follow-up questioning should be meticulously documented on the DHQ. If a donor is determined to be ineligible during follow-up questioning, the reason for deferral should be documented in a designated area on the DHQ. If a donor is determined to be eligible during follow-up questioning for an affirmative response to a question(s), a detailed explanation for each question must be documented in sufficient detail in a designated area on the DHQ.

Example 1: A donor answers “yes” to DHQ Q2, “Are you currently taking an antibiotic?”

Sample documentation: “Donor taking tetracycline daily for acne prophylaxis: OK per SOP.”

Example 2: A donor answers “yes” to DHQ Q39, “Have you ever had hepatitis?”

Sample documentation: “Donor had hepatitis A at 7 years old; OK per SOP.”

Example 3: A donor answers “yes” to aDHQ Q12, “Since your last donation have you been outside the United States or Canada?”

Sample documentation: “12d, donor traveled to rural area in Quintana Roo, Mexico 6 weeks ago; malaria risk; 12 months deferral.”

Example 4: A donor answers “Yes” to aDHQ Q12, “Since your last donation have you been outside the United States or Canada?”

Sample documentation: “12b, donor traveled to Africa – Cairo, Egypt – one month ago for three days; OK per SOP.”

Example 5: A donor answers “Yes” to aDHQ Q9, “Since your last donation have you had any new medical problems or diagnoses?”

Sample documentation: “Donor diagnosed with hypertension 2 months ago, well-controlled on meds, normal BP today; OK per SOP.”

Abbreviated Donor History Questionnaire: An abbreviated version of the DHQ (aDHQ) that is intended to be used by repeat blood donors.

When is a donor considered to be a repeat blood donor?

A blood donor is eligible to use the aDHQ if certain defined donor criteria are met and if the blood collection facility has a system in place that can determine when it is appropriate to use the aDHQ.

Repeat Donor Criteria: A donor who has previously donated two times, one donation of which occurred within the previous six months. Both donations must have been screened using the full-length DHQ.

Is it necessary to administer the full-length questionnaire once a donor is classified as a repeat donor?

Once the donor qualifies for the aDHQ, there is no need to administer the full-length questionnaire as long as the donor continues to qualify for the abbreviated version. However, if the donor does not qualify, ? for example, if the last donation was greater than 6 months ? the full-length DHQ MUST be administered. If the donor was deferred at the last donation, the full-length questionnaire will be administered.

From time to time, new donor history questions will be added. The new questions must be added to the full-length and the abbreviated DHQ. The new questions will remain on the aDHQ for one year from the date the question was added. If the question must be asked at each donation, the question will remain indefinitely on both DHQs.

How will the blood collection facility track whether the full-length questionnaire or the abbreviated questionnaire should be administered, especially at mobile collection units?

The blood collection facility must have a system to determine when it is appropriate to administer the abbreviated questionnaire and when the full-length questionnaire must be administered. Some of the items that the system must be able to determine are: how many times the donor has donated, the time interval since their last donation, which questionnaire was utilized at each donation, the full-length questionnaire or the abbreviated questionnaire.

What action should be taken when it is determined that an incorrect questionnaire has been administered or if a questionnaire is incomplete?

The blood collection facility must have a standard operating procedure describing actions in this circumstance. If a full-length questionnaire has been administered when a donor qualified for an abbreviated questionnaire, no additional action is required with regard to donor or product suitability. If an abbreviated questionnaire was administered when a full-length questionnaire should have been administered, the SOP must ensure that the donor unit is not made available for distribution (quarantined) until donor suitability

issues have been resolved. FDA regulations specify that donor eligibility must be made on the day of donation. In the instance in which eligibility was incorrectly determined using the aDHQ, if the donor can be re-screened and eligibility can be determined using the full-length questionnaire on the day of donation, the components may be released if otherwise suitable. If the unit has already been distributed, then it should be treated as post-donation information, including submission of a biological product deviation report to the FDA if appropriate. Blood collection facilities should follow current, applicable FDA Guidance, which can be found at:

Guidance Documents:

☞ <http://www.fda.gov/cber/guideline.htm>

☞ <http://www.fda.gov/cber/memo.htm>

General CBER Information:

☞ <http://www.fda.gov/cber/>

☞ <http://www.fda.gov/cber/reading/htm>

User Brochure Format: The User Brochure is modular and uses flow-charting to guide the donor historian through the donor questionnaire process. Each question is a complete section that begins on a new page, so that changes to the DHQ and the aDHQ can be easily modified in the User Brochure. Each section contains the following information:

Question: Question number and the question.

Donor Eligibility: This section provides additional information to the donor historian on donor eligibility requirements for each question.

Note: Optional field; additional relevant information relating to the donor question.

Flow Chart: Each question is flow-charted using standard flow-charting symbols.

Square -- Statement

Diamond -- Question/decision point

Oval -- Action

Arrow -- Move to the next question

Each question ends with an ARROW that indicates to “move to the next question;” however, blood centers must follow their established policies concerning whether or not the donor suitability process is terminated when it is known that the donor will be deferred.

Donor Deferrals: For some questions, a “yes” answer calls for a required deferral, either indefinitely or for a specified period of time. A required deferral is designated in the flow chart by the Action “*Defer donor.*” The donor historian may need to refer to the blood center’s SOP to determine if and when the donor may be eligible to return.

For other questions, a “yes” answer may not require a deferral; rather, it may trigger a line of questioning to determine if the donor is eligible. The donor historian will need to refer to the blood center’s SOP for follow-up questions to determine suitability. This type of deferral is designated in the flow chart by the Action “*Defer donor per SOP.*” For example, if a donor answers “yes” to the question “In the past 12 months, have you had a

blood transfusion?,” certain blood centers may ask further questions regarding the kind of blood. Some blood centers may allow donors with confirmed receipt of autologous blood only to donate. Other centers may simply defer all donors who received blood in the last 12 months, regardless of whether the blood was allogeneic or autologous.

Each blood center’s SOP must define how the donor responses to the follow-up questions will be documented on the DHQ. Responses should be documented with sufficient detail to determine the reason for donor acceptance or deferral.

References: A list of references concerning donor eligibility is included at the end of the questions.